

NaviENT Receives FDA 510(K) Clearance



Toronto, Ontario, Canada, September 8, 2017
ClaroNav Kolahi Inc. (CKI), a subsidiary of ClaroNav, announces that NaviENT, its Surgical Navigation System, received FDA 510(K) clearance.

CKI is pleased to announce that it has received FDA 510(K) clearance from the Food and Drug Administration (FDA) to market and sell NaviENT in the United States. Over the coming months the company will offer the product for sale to hospitals, clinics and offices performing endoscopic sinus surgery and skull base surgery in the US. NaviENT has been granted CE mark approval for the European market, Taiwan and Korean FDA and Health Canada approval in 2016.

NaviENT is an Image-Guided Surgical navigation system, which helps ENT surgeons with identifying anatomic structures in the transnasal interventions. It enables surgeons to avoid complications and confidently make more informed decisions during FESS and skull base surgeries. NaviENT also results in cost saving by shortening length of hospitalization compared to non-navigated surgeries.

“Surgical Navigation system is a precious aid in primary surgery and its benefits are widely accepted among neurosurgeons and otolaryngologists. Its 3D anatomical structure localization and visualization capability assists the surgeons to target specific anatomy and avoid complications in

highly variable sinus anatomy. However, despite its obvious advantages, many surgeons are hesitant in adapting the technology, blaming its cumbersome operation and high price tag.” said Ahmad Kolahi, CEO of CKI “NaviENT is an innovative navigation system designed in close collaboration with experienced rhinologists to address shortcomings of the current navigation systems. Our primary goal is to offer an intuitive, accurate and affordable state-of-the-art ENT navigation system and make it standard-of-care in the ENT field.”

Study shows that surgical navigation systems would allow more complete dissection, obviating the need for revision surgery. The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) endorses the use of image-guided surgery for many FESS and skull base procedures.

“NaviENT was designed in concert with rhinologists to develop the most user-friendly, accurate, reliable, and affordable navigation system on the market. It is clear that they have achieved their goals. In this case, using is believing.” said Peter Catalano, MD, FACS, FARS, Professor of Otolaryngology, Chief of Otolaryngology, St. Elizabeth’s Medical Center, Boston. “NaviENT is a most welcome addition for the ENT surgeon. This portable system provides quick set-up and accurate registration, a user-friendly interface, and versatile re-usable intra-operative tools. In addition, there are no disposable costs and the sale price is extremely affordable. NaviENT will effectively bring surgical navigation to every corner of the globe.”

For more information about the NaviENT, please visit www.claronav.com/navient

About ClaroNav Kolahi Inc. (CKI)

CKI is a subsidiary of ClaroNav, a medical device hardware and software company headquartered in Toronto, Canada, and is represented worldwide by authorized distributors. ClaroNav and CKI are deeply committed to product quality and safety, and certified as compliant with ISO 13485, ISO 14971 and CMDCAS. CKI is dedicated to innovation and developing state-of-the-art surgical navigation systems to enable surgeons to confidently make more informed decisions for better patient outcomes. For more information, visit www.claronav.com.

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